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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/301,766	04/29/1999	EIJIRO WATANABE	0020-4559P	6045
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BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			KRUSE, DAVID H	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 08/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/301,766	Applicant(s) WATANABE ET AL.	
	Examiner David H. Kruse	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-10,16-23,28 and 29 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1,4,5,8-10,16-23,28 and 29 is/are rejected.
7) ☒ Claim(s) 6 and 7 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is in response to the Amendment and Remarks filed 2 June 2006.
2. The objection to claim 16 is withdrawn in view of Applicant's amendment to correct formal matters.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

4. Claims 1, 4, 5, 8-10, 16-23 and 28-29 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 2 December 2005. Applicant's arguments filed 2 June 2006 have been fully considered but they are not persuasive.

Applicant argues that absent sound scientific reasoning or evidence to the contrary, the Examiner must accept as true allegations made in the specification (In re Marzocchi, 169 USPQ 137 (CCPA 1971)) (page 7, 1st paragraph of the Remarks). In response the Examiner believes that sound scientific and legal reasoning has been provided on the record.

Applicant argues that the specification describes the complete amino acid sequence of at least two raffinose synthase proteins (SEQ ID NO: 3 and SEQ ID NO: 5). Applicant argues that the specification also discloses a partial amino acid sequence of two additional raffinose synthase proteins (SEQ ID NO: 1 and SEQ ID NO: 7). Applicant argues that the specification describes how to obtain a raffinose synthase cDNA using the polymerase chain reaction amplification method using particular primers described by sequence, and discloses plant sources with which those primers may be used. Applicant argues that the specification further describes how to express the CDNA in both bacterial and plant hosts. Applicant argues that the specification provides an assay for raffinose synthase biological activity. Applicant argues that the specification states, based upon the high degree of amino acid sequence homology (i.e. about 70% identity or higher), it is expected that the protein of SEQ ID NO: 3 will exhibit raffinose synthase activity (page 7, 2nd paragraph of the Remarks). These arguments are not found to be persuasive. As directed to SEQ ID NO: 7, the lack of adequate written description has been extensively addressed in previous Office actions. A description of an incomplete coding sequence does not describe a nucleic acid sequence encoding a raffinose synthase enzyme. See *Brenner v. Manson*, 383 U.S. 519 (1966), which states "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point--where specific benefit exists in currently available form--there is insufficient justification for permitting an applicant to engross what may prove to be a broad field."

Art Unit: 1638

Applicant, at the time of the invention, had not provided substantial evidence that the amino acid sequence of SEQ ID NO: 3 describes a raffinose synthase. As previously stated in the Office action mailed 11 August 2003, the art teaches that at the time of Applicant's invention, one of skill in the art cannot assume the function of the polypeptide encoded by an isolated nucleic acid solely based on sequence similarity to a known polypeptide sequence (see Duggleby 1997, previously cited, and Richmond *et al* 2000, Plant Physiology 124: 495-498, see paragraph spanning right and left column on page 497). As directed to isolated nucleic acids encoding raffinose synthase enzymes isolated from "beet" or "mustard or rapeseed", merely describing a method by which a nucleic acid may be isolated does not describe the nucleic acid encoding a raffinose synthase as asserted by Applicant. See also, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. At the time of Applicant's invention, only one other plant raffinose synthase had been known in the prior art, that being from cucumber. It is unclear from Applicant's specification that one skilled in the art could have made the asserted correlation between structure of an encoded amino acid sequence and a plant raffinose synthase

Art Unit: 1638

function, as no identifying characteristics of a plant raffinose synthase protein were known at the time of the instant invention.

Applicants argue that the disclosure in the companion application no. 08/992,914, which shows that the CDNA obtained from broad bean (*V faba*, SEQ ID NO: 1 of the '914 application) also encodes a protein having raffinose synthase activity. (see Table 1 of that specification.), and that the *V faba* sequence has about 62% amino acid sequence identity to SEQ ID NO: 5 (from mustard) of the present application (see Table 2 of the Watanabe Declaration II attached), thus the present record now contains evidence that demonstrates unequivocally that Applicants' assertion in the present specification that a protein having at least 70% identity to SEQ ID NO: 3 (or 5 or 7) has raffinose synthase activity is correct (page 8, 2nd paragraph of the Remarks). This argument is not found to be persuasive for the reasons given above.

Applicant argues that the showings of the Watanabe Declaration, and the disclosure of the '914 application, that two of two proteins identified as putative raffinose synthases according to the teachings of the present specification do indeed have that activity, the Examiner must withdraw the present rejection (page 8, 3rd paragraph of the Remarks). This argument is not found to be persuasive. Each application is examined upon its own merits. Even given the 70% sequence identity at the amino acid level, Applicant has not describe what structural features would describe the genus of encoded raffinose synthase encoding nucleic acids as broadly claimed.

Applicant argues that the written description requirement can be adequately met in the complete absence of any working example or any demonstration of actual

Art Unit: 1638

reduction to practice, See, e.g. *Falkner v. Inglis*, Case no. 05-1324 (Fed. Cir. 2006), copy attached (page 9, 4th paragraph of the remarks). This argument is not found to be persuasive in the instant case. At page 8 the court states that written description is a question of fact, judged from the perspective of one of ordinary skill in the art as of the relevant filing date (See *Vas-cath. Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991)). At page 15 the court teaches that in the context of interpreting 35 U.S.C. § 102(b), the Court held that "the word 'invention' must refer to a concept that is complete, rather than merely one that is 'substantially complete'" (*Pfaff v. Wells Elecs.*, 525 U.S. 55, 66 (1998)). The fact is that the invention of the instant claims would not have been, from the perspective of one of ordinary skill in the art as of the relative filing date, a complete concept.

Applicant argues that the specification also describes a set of PCR primers that can be used to obtain clones from enumerated genera of plants, tat there is a test for actual raffinose synthase activity described in the specification so that clones so obtained can be confirmed in their activity. Applicant argues that there is evidence of record that one of ordinary skill in the art can distinguish a raffinose synthase protein from the stachyose synthase and seed imbibation proteins of different utility based upon sequence homology to the reference sequences in the specification in the manner set forth in the specification (page 9, 1st paragraph of the Remarks). These arguments are not found to be persuasive for the reason given above.

5. Claims 1, 4, 5, 8-10, 16-23 and 28-29 remain rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for an isolated nucleic

acid encoding the amino acid sequence of SEQ ID NO: 5, plants transformed therewith and methods of using such isolated nucleic acid, does not reasonably provide enablement for other isolated nucleic acids encoding raffinose synthase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reason of record as set forth in the last Office action mailed 2 December 2005. Applicant's arguments filed 2 June 2006 have been fully considered but they are not persuasive.

Applicant argues that there is evidence of record in the application, though not previously provided in Declaration form, in Table 1, Table 2 and Figure 1 filed with Applicants' paper of February 11, 2004, that demonstrates that the degree of sequence identity among raffinose synthases is at least 50%, the degree of sequence identity among stachyose synthases is at least 64%, and the degree of sequence identity between a raffinose synthase and a stachyose synthase or seed imbibition protein is only as high as 44%, thus, one of ordinary skill in the art, merely comparing an amino acid sequence of a protein to SEQ ID NO: 3 (or 5 or 7) can easily preliminarily determine whether or not it is a raffinose synthase (% identity > 50%) or a stachyose synthase (% identity <44%) or a seed imbibition protein (% identity < 39%) (page 10, 4th paragraph of the Remarks). This argument is not found to be persuasive. *In re Wands*, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of

Art Unit: 1638

direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims. At the time of Applicant's invention, the argued facts above were not know to those of skill in this art. The instant specification does not provide such guidance as to how one skilled in the art would distinguish raffinose synthases from stachyose synthases. As stated supra, at the time of Applicant's invention, only one other plant raffinose synthase encoding nucleic acid had been know in the prior art, that being from cucumber.

Applicant argues that once a protein is identified as a putative raffinose synthase, the artisan can then perform the expression and assay tests described in the specification to confirm this preliminary determination (page 11, 1st paragraph of the Remarks). Applicant argues that the level of ordinary skill in the art of isolating genes from plants and characterizing the encoded proteins is generally accepted to be high, therefore, the experimentation described in the specification as needed to obtain clones from diverse plants, compare their sequences to one of SEQ ID NO: 3, 5 or 7 to identify putative raffinose synthases, express the encoded proteins and then perform the activity assay as described in the specification is well within the skill of the ordinary artisan (page 11, 3rd paragraph of the Remarks). Applicant argues that the specification teaches that sequence homology provides a hypothesis that a protein is a raffinose synthase and that the specification teaches a biochemical assay for raffinose synthase activity that one of ordinary skill in the art may apply to confirm that hypothesis (page 11, 4th paragraph of the Remarks). These arguments are not found to be persuasive.

Art Unit: 1638

Peterbauer *et al* (2002) teach that those of skill in the art recognized that isolating and assaying raffinose synthase enzymes was difficult because the enzyme was labile (see paragraph spanning pages 839-840). Peterbauer *et al* (2002) teach that *Pisum* raffinose synthase has structural and biochemical similarities to α -galactosidases (see for example Figure 1 on page 841). Peterbauer *et al* (2002) teach that raffinose synthase would be recognized as [a] neutral α -galactosidase if assayed only with *p*-nitrophenyl galactopyranoside or galactinol (page 845, left column). Hence, it remains unclear that it would not have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to make and use the invention as broadly claimed.

Applicants argue that, if anything, they (Peterbauer *et al* (2002) improve the ability of a skilled artisan to distinguish a raffinose synthase from a stachyose synthase, at page 841, right column, point out "a block of about 80 amino acids, which is exclusively present in stachyose synthases." (page 12, 2nd paragraph of the Remarks). This argument is not found to be persuasive because it is Applicant's responsibility to enable the claimed invention, and not post-filing art that teaches a critical feature to distinguish raffinose synthases from stachyose synthases.

Conclusion

6. Claims 6 and 7 are allowed.
7. Claims 1, 4, 5, 8-10, 16-23 and 28-29 remain rejected.
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink that reads "David H. Kruse". The signature is written in a cursive, flowing style with a large initial "D".

David H. Kruse, Ph.D.
18 August 2006

Art Unit: 1638

10. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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